

# Linguistic and cultural validation of Ureteral Stent Symptom Questionnaire in Hindi

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## ABSTRACT

**Introduction:** In the year 2003, Joshi *et al.* developed a validated outcome assessment tool to measure the ureteral stent-related symptoms. The original English language Ureteral Stent Symptom Questionnaire (USSQ) has been validated in various languages worldwide. Our objective was to develop the USSQ in Hindi, a commonly used language in India, by validating it in patients undergoing ureteroscopic lithotripsy.

**Materials and Methods:** A final Hindi version of the USSQ was derived from the original English version to apply to the study population by translation, back translation, and face-to-face interviews. The Hindi and English versions were completed by 70 patients undergoing ureteroscopic lithotripsy with stent *in situ*, on postoperative days 7 and 8, and 4 weeks after stent removal. Similarly, discriminant validity was checked among 50 healthy individuals. A detailed statistical analysis was used to correlate results (Cronbach's  $\alpha$  coefficient, Spearman's correlation, and Mann-Whitney U-test).

**Results:** A total of 70 patients were enrolled in the study and 61 completed the final assessment. The median age was 35 years (range: 18–60 years). The USSQ domain scores with the stent *in situ* were higher than poststent status. The test-retest reliability checked by Cronbach's  $\alpha$  coefficient ( $>0.44$ ) and Spearman's correlation coefficient ( $>0.44$ ) were acceptable to good. We found high discriminant validity of the questionnaire between patients with stent and the healthy controls ( $P < 0.05$ ).

**Conclusion:** Our results demonstrate satisfactory validity for the Hindi version of the USSQ for the assessment of quality of life in patients with stent. This is ready for application in the clinical studies and the future stent-related research in Hindi language.

## INTRODUCTION

In the year 1967, Zimskind first placed a straight silicon tube into the ureter endoscopically to relieve pelvicalyceal system obstruction and called it a 'ureteral splint'.<sup>[1]</sup> Up to 76% of patients are found to experience discomforts such as urinary frequency, dysuria, pain, incontinence, and hematuria because of the indwelling ureteral stent.<sup>[2]</sup> Most of these are subjective findings, which may vary according to the patient's perception; hence, a universally acceptable tool to measure these

symptoms is necessary. In 2003, Joshi *et al.* developed a standard for stent-related symptom assessment named Ureteral Stent Symptom Questionnaire (USSQ), containing 38 items under six domains that evaluate subjective quality of life objectively.<sup>[3]</sup> A high score indicates that symptoms are more bothersome to the patient. Later on, the questionnaire has been translated, validated, and published in French,<sup>[4]</sup> Italian,<sup>[5]</sup> Korean,<sup>[6]</sup> Brazilian,<sup>[7]</sup> and other languages.

Hindi is the fourth most commonly spoken language in the world with >329 million users and large numbers of them

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are conversant in Hindi language only.<sup>[8]</sup> Our objective was to develop the USSQ in Hindi language and to check its validity in patients undergoing ureteroscopic lithotripsy.

## MATERIALS AND METHODS

The present study was conducted from October 2016 to June 2017. The study was approved by the Institutional Ethics Committee. Reframing of the original English version of USSQ in Hindi language was done by two independent translators (one Master of Surgery and other Master of Business Administration in Hospital Management) who are proficient in Hindi and English. The questionnaire was translated back into English language by two urologists. The translated and back-translated versions were further checked to make minor changes in language and grammar. The final draft was developed after face-to-face interview among three men and women with indwelling stents and after removing the discrepancies. Before the application of the translated version of USSQ, the validity was checked among 20 participants (10 males and 10 females). The final Hindi version of USSQ was validated by administration on the study population. The required sample size was determined based on the correlation coefficient of 0.56 (found in the Italian validation of USSQ) with the assumption of alpha – 0.05 and beta – 0.10.

Adult patients over 18 years of age and able to read and understand Hindi, who underwent ureteral stent placement after semirigid or flexible ureteroscopy with or without LASER lithotripsy at our center, were included in the study after taking informed written consent. The exclusion criteria included (1) ongoing treatment for recurrent urinary tract infection, lower urinary tract symptom, chronic prostatitis, and chronic pelvic pain syndrome; (2) history of, or ongoing treatment for, stress/urge/mixed urinary incontinence or overactive bladder; (3) pregnancy; (4) chronic urethral obstruction; (5) concomitant medication with  $\alpha$ -blockers, anticholinergics, analgesics, and other drugs interfering with lower urinary tract function; and (6) ureteroscopic procedure with complication such as ureteral perforation or incomplete stone clearance.

A total of 70 patients, male ( $n = 35$ ) and female ( $n = 35$ ), were enrolled in the study fulfilling the inclusion and exclusion criteria. The 5Fr, same type double-J stent made up of polyurethane, was placed after procedure. The stent coil and position was checked under fluoroscopy so that it does not cross the midline in the bladder.

All the patients were asked to complete the original English language USSQ and also the Hindi version of USSQ on day 7<sup>th</sup> and on day 8<sup>th</sup> of the procedure to analyze the internal consistency. All patients were asked to complete Hindi language USSQ after 4 weeks of stent removal. To improve comparability, 50 healthy individuals without any medical

illness were asked to complete Hindi version of USSQ. All incomplete questionnaires were excluded from the final assessment. Individual domain score was calculated by summing up the scores in each domain according to the recommendation by authors of original USSQ.

The internal consistency was checked by Cronbach's  $\alpha$  coefficient in each domain for evaluating reliability. The test-retest reliability between 7<sup>th</sup> and 8<sup>th</sup> day was assessed by Spearman's coefficient test. The Mann-Whitney U-test was considered to determine the sensitivity to change between various domains of *in situ* and postremoval time.

## RESULTS

Before the application of the translated version of USSQ, the validity was checked among 20 participants (10 males and 10 females) and the results confirmed that the questions were clear and well understood by the patients. A total of 70 cases were enrolled in the study after taking written consent. Those who submitted incomplete questionnaires ( $n = 4$ ) (three patients had left last two domains blank and one patient left the last three domains unfilled) and those who lost to follow-up after stent removal ( $n = 5$ ) were not considered in the final assessment. Thus, 61 cases were left for the final analysis [Table 1]. The median age was 35 years (range: 18–60 years) with a urinary symptom score of 29 and 18, at 7<sup>th</sup> day and poststent removal, respectively. Body pain score was 18 on the 7<sup>th</sup> day and 17 at 8<sup>th</sup> day. None of our patients reported pain at 4 weeks after removal of the stent. The USSQ score at stent *in situ* duration was higher than the poststent removal duration.

The value of the Cronbach's  $\alpha$  coefficient [Table 2] signifies that the questions in each domain were well interrelated, but independent. Most of the cases were sexually inactive during stented duration and most of them had abandoned it after stent placement ( $n = 42, 68.9\%$ ).

Positive correlation was found by Spearman's correlation coefficient for assessing the test-retest reliability [Table 3] of all domains at two moments with stent *in situ* and was reasonably high for urinary symptoms and body pain.

The sensitivity to change was analyzed at two different moments, one with stent *in situ* and other poststent

**Table 1: Descriptive statistics of each domain score: median (range)**

Domain	7 <sup>th</sup> day stent <i>in situ</i>	8 <sup>th</sup> day stent <i>in situ</i>	Post DJR at 4 weeks
Urinary symptoms	29 (21-40)	28 (18-39)	16 (13-21)
Body pain	18 (7-17)	17 (7-26)	2 (2)
General health	12 (9-17)	13 (7-17)	6 (5-9)
Work performance	6 (4-10)	7 (2-9)	5 (3-8)
Sexual matter	2 (1-7)	2 (1-7)	2 (1-7)
Global QOL	5 (2-7)	5 (2-7)	2 (2-4)

QOL=Quality of life, DJR=Double J stent removal

**Table 2: Reliability of Ureteral Stent Symptom Questionnaire Hindi version**

Domain	Internal consistency Cronbach's $\alpha$		Test retest reliability (Spearman's correlation coefficient)
	<i>in situ</i>		
	7 <sup>th</sup> day stent	8 <sup>th</sup> day stent	
Urinary symptoms	0.80	0.83	0.86
Body pain	0.87	0.80	0.65
General health	0.76	0.73	0.73
Work performance	0.70	0.62	0.44
Sexual matter	0.30	0.44	0.57
Global QOL	Not applicable	Not applicable	0.62

QOL=Quality of life

**Table 3: Correlation of all domains with *in situ* stent at two different moments (day 7<sup>th</sup> and day 8<sup>th</sup>) (Spearman's coefficient)**

Domain	Urinary symptoms	Body pain	General health	Work performance	Sexual matter	Global QOL
Urinary symptoms	1/1					
Body pain	0.77/0.67	1/1				
General health	0.80/0.61	0.67/0.46	1/1			
Work performance	0.64/0.49	0.57/0.33	0.45/0.35	1/1		
Sexual matter	0.54/0.25	0.34/0.18	0.54/0.11	0.23/0.18	1/1	
Global QOL	0.32/0.66	0.10/0.42	0.27/0.44	0.16/0.30	0.27/0.16	1/1

QOL=Quality of life

removal (Man-Whitney U-test). There was a statistically significant difference in all domains except for sexual matter (<0.05 and 0.16) where it did not reach a statistically significant level. A total of 88.5% (n = 54) cases were sexually inactive due to stent or because of some other reasons in our study.

The difference in domain urinary symptoms, bodily pain, general health, and work performance was highly significant (P < 0.001) between case and control groups [Table 4].

Discriminant validity of the questionnaire [Table 5] was assessed by comparing the cases with age- and sex-matched healthy control groups, showing it as a valid measure to discriminate between patients with stent and healthy controls.

The control group was found to have significantly lower USSQ score as compared to cases among all domains except the sexual matter domain.

Furthermore, the quality of life was differed significantly between the two groups [Figure 1]. Quality-of-life analysis indicates that none of our cases were comfortable with stent *in situ* but after stent removal; 77% felt satisfied.

## DISCUSSION

Ureteral stent placement is routine following various endourological procedures for upper tract calculi. However, stents are associated with morbidity and stent-related symptoms affect the patients' quality of life,<sup>[9,10]</sup> in about 76% of patients.<sup>[2]</sup> The common features are dysuria, urinary urgency, hematuria, stent-associated pain, and

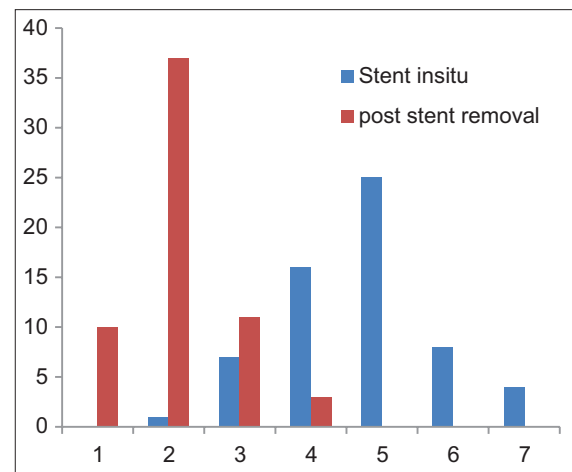


Figure 1: Quality of life

difficulty in performing routine activities<sup>[11]</sup> and are usually transient during the stent indwelling period.<sup>[12]</sup> In the year 2003, a validated and comprehensive instrument to assess the stent-related problems was developed by Joshi et al.<sup>[13]</sup> The linguistic validation of the original USSQ has been completed in many languages worldwide. In this study, we have evaluated the cross-cultural application and validation of the Hindi language version of USSQ for use in Asian and especially in the Indian population. By performing translation and back-translation exercise and further correction in Hindi version, we developed the Hindi version that is comprehensive, valid, and applicable to the Hindi-speaking population. An ideal stent material which does not cause any stent-related symptoms is yet to be discovered and research in this domain is ongoing. This questionnaire could be suitable for use as an outcome measure during the current and any future research in this field.

In our study, the median age of distribution was 35 years (range: 18–60 years) and was younger compared to the Spanish version’s validation study. All of our cases were able to read and understand Hindi. Completing the English version of USSQ was troublesome for them requiring assistance by us or by the relatives. The discrimination validity was found to be significant among patients with ureteral stents and healthy individuals indicating its high ability to identify stented population. Furthermore, similar results were reported in the Italian, Korean, and Spanish linguistic validation studies.<sup>[4-6,13]</sup>

We demonstrated good internal consistency among the questions within all domains, making the questionnaire reliable, except in the sexual matter domain. The test–retest reliability was good and is comparable to other language validation studies. However, we have considered two moments 24 h apart for the test–retest reliability, and this could raise a small possibility of recall bias in our study, while the original USSQ study and Italian study kept interval of 4 weeks and Korean language validation kept a gap period of 2 weeks. We usually discharge patient on postoperative

day 2 from hospital, and removal of stent at 2–3 weeks of the procedure is our routine practice.

We first assessed the score on day 7<sup>th</sup> of procedure, providing enough time to patient for assessing their symptoms. The poststent removal assessment was done 4 weeks after stent removal giving enough healthy lifestyle dwelling before answering the questionnaire.

We found a moderate correlation among all domains compared at 7<sup>th</sup> day and 8<sup>th</sup> day after the procedure and relatively high correlation between urinary symptom and pain. This was more than the Korean version validation. The reason was short gap of 24 h only between the two assessments. Similar results were described in other author studies also [Table 6]. This indicates the definite impact of ureteral stent on day-to-day life irrespective of translation used.

We have avoided the cases with complication during surgery or those giving a history of significant urological comorbidity, therefore, improving accurate, objective assessment of symptoms. The convergent ability of the Hindi version with IPSS, questionnaire on incontinence, and other quality-of-life index were difficult to check in our cases, as there are no Hindi validated versions for these questionnaires. Most of our patients were not able to understand the English language, therefore, could not complete the English USSQ themselves. This limits the comparability between English and Hindi versions of USSQ. USSQ contains 38 questions under six domains demanding time to complete it. Our four (*n* = 4) patients had left the questionnaire incomplete (three had left last two domains unfilled and one patient had left last three domains blank).

We found a moderate correlation among all domains ranging 0.35–0.80, implying nonloading of the items, except for sexual matter. Meanwhile, most of our patients were not active sexually, affecting the results in this domain. In a Korean study, 10.8% and 18.5% of cases were sexually active at 1 and 2 weeks of stenting. The Italian language validation study described 66.7% at 4 weeks. In our study, only 9.8% of cases were sexually active at 1 week, which was comparable to Korean study. As observed in other studies, very few patients were sexually active with an indwelling stent. The reasons could be hesitation in having sex after

**Table 4: Sensitivity to change of the Hindi version of Ureteral Stent Symptom Questionnaire (Mann-Whitney U-test)**

Domains	P	
	7 <sup>th</sup> day versus postremoval	8 <sup>th</sup> day versus postremoval
Urinary symptoms	<0.001	<0.001
Body pain	<0.001	<0.001
General health	<0.001	<0.001
Work performance	<0.001	<0.001
Sexual matter	0.010 (<0.05)	0.16
Global QOL	<0.001	<0.001

QOL=Quality of life

**Table 5: Discriminant validity of Hindi version of Ureteral Stent Symptom questionnaire (Mann-Whitney U-test)**

Domains	Cases (7 <sup>th</sup> -day stent <i>in situ</i> )	Controls	P
Age (median), years	35	35	0.81
Urinary symptoms	28 (21-40)	13 (11-16)	<0.001
Body pain	17 (7-26)	2 (2)	<0.001
General health	13 (7-17)	7 (5-8)	<0.001
Work performance	7 (2-9)	5 (3-7)	<0.001
Sexual matter	2 (1-7)	3 (1-7)	<0.05
Global QOL	5 (2-7)	2 (1-4)	<0.001

QOL=Quality of life

**Table 6: Domain scores assessed in other studies**

Author	Giannarini Week 1	Giannarini Week 4	Joshi Week 1	Joshi Week 4	Park Week 1	Park Week 2	Present study Week 1	Present study 8 <sup>th</sup> day
Urinary symptoms	32	22	26.9	28.3	28	27	29	28
Body pain	38	25	23.05	22.2	18.5	18	18	17
General health	15.5	11	10.73	12.8	12	11	12	13
Work performance	6	3.5	9.9	15	7.5	6	6	7
Sexual matters	5	5	3.99	4.7	NR	NR	2	2
QOL	5	4	NR	NR	4	5	5	5

QOL=Quality of life, NR=Not reported

stent placement, risks of having complications and safety issues as well as small possibility of their reluctance to discuss sexual behavior.<sup>[14]</sup> Poststent removal sexually active cases were 26% at 4 weeks, indicating patients were uncertain, shortly after stent removal, about resuming the sexual activity, and fear of sexual activity might have persisted after stent removal. Educating and counseling the patients and performing studies with a larger sample size can better help in understanding the social and cultural factors on this issue.

## CONCLUSION

Our results satisfactorily demonstrate that the new Hindi version of the USSQ as a valid and reliable instrument for the assessment of stent-related symptoms. This Hindi version can be used as a valid outcome measure in assessing the stent-related symptoms in a clinical setting and research in the Indian/Asian population. Further clinical studies in the Indian/Asian settings would be useful to provide additional robust data.

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